UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	**MDL No. 2419**
	Master Docket No. 1:13-md-2419- RWZ
This Document Relates to:	
Armetta, et al v. Box Hill Surgery Center, LLC, et al. **No. 1:14-cv-14022-RWZ**	
Bowman, et al v. Box Hill Surgery Center, LLC, et al. **No. 1:14-cv-14028-RWZ**	
Davis, et al v. Box Hill Surgery Center, LLC, et al. **No. 1:14-cv-14033-RWZ**	**PLAINTIFFS' OPPOSITION TO DEFENDANTS' BOX HILL SURGERY CENTER, LLC, RITU T. BHAMBHANI, M.D., AND RITU T. BHAMBHANI, M.D., LLC, MOTION TO DISMISS PURSUANT TO FED. R. CIV. P. 12(b)(6)**
Dreisch, et al v. Box Hill Surgery Center, LLC, et al. **No. 1:14-cv-14029-RWZ**	
Farthing, et al v. Box Hill Surgery Center, LLC, et al. **No. 1:14-cv-14036-RWZ**	
Kashi, et al v. Box Hill Surgery Center, LLC, et al. **No. 1:14-cv-14026-RWZ**	
Torbeck, et al v. Box Hill Surgery Center, LLC, et al. **No. 1:14-cv-14023-RWZ**	
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INTRODUCTION

It is undisputed that the widespread outbreak of fungal meningitis, which gave rise to this multi-district litigation, was caused by contaminated preservative-free methlyprednisolone acetate ("MPA") compounded by New England Compounding Center, Inc. ("NECC") being administered to patients at over 70 pain clinics, orthopedic practices and hospitals,[1] including the Box Hill Defendants.[2] Liability extends to the health care providers and facilities that purchased the contaminated products and distributed them to their patients. Despite extensive guidelines setting forth doctors' and clinics' responsibilities when outsourcing risky compounded drugs, the Box Hill Defendants failed to perform any due diligence. Instead, the Box Hill Defendants mail-ordered hundreds of vials of prescription preservative-free MPA from NECC without any reasonable effort to assess and evaluate NECC's ability to aseptically make, package and dispense preservative-free MPA.

The Complaints, filed by the Plaintiffs in August, 2014, set forth in great detail the reasons why the healthcare providers, including the Box Hill Defendants, have responsibility for Plaintiffs' injuries and harm. Without Box Hill's negligent and reckless conduct in mail-ordering and purchasing contaminated steroids and administering them to patients without performing any due diligence the Plaintiffs would not have received contaminated MPA in their spinal columns causing them to suffer serious injuries and in four cases death. The factual and legal allegations in the Complaints are thorough, well-pleaded, and sufficiently state claims upon which relief can be granted. Plaintiffs plead an actionable multi-count case that the Box Hill Defendants without

[1] *See* CDC, Multistate Fungal Meningitis Outbreak Investigation, http://www.cdc.gov/hai/outbreaks/meningitis-map-large.html (Visited March 2014); *see also* FDA, Multistate outbreak of fungal meningitis and other infections, http://www.fda.gov/%20Drugs/DrugSafety/FungalMeningitis/default.htm; Smith, Rachel M., et al., *Fungal Infections Associated with Contaminated Methylprednisolone Injections*, N Engl J Med 2013; 369:1598-1609 (Oct. 24, 2013).

[2] "Box Hill Defendants," "Defendants," and/or "Box Hill" refers collectively to Box Hill Surgery Center, LLC, Ritu T. Bhambhani, M.D., and Ritu T. Bhambhani, M.D., LLC.

due, proper and necessary qualification of NECC's competence and ability acquired and administered adulterated preservative-free MPA from NECC, and, importantly, did so by submitting prescriptions to NECC that violated Massachusetts' controlled substances law[3], Massachusetts' consumer protection law[4], Maryland case law on strict product liability and Maryland statutory law on consumer protection[5].

The Complaints are lengthy and describe in a detailed manner how the Box Hill Defendants' conduct contributed to the outbreak. For example, the Complaints allege that Defendants failed to exercise reasonable care to ensure that the drugs they purchased and administered to Plaintiffs were manufactured in compliance with applicable pharmaceutical laws. The Complaints allege that the Box Hill Defendants failed to perform the necessary diligence to determine the safety and quality of NECC's drugs and failed to determine if NECC could properly provide sterile, preservative-free drugs for administration to patients. The Complaints also set forth how the Box Hill Defendants failed to conduct sufficient due diligence to determine whether NECC was a reputable and safe supplier of sterile injectable compounds and the Complaints assert that Box Hill Defendants purchased compounded drugs in bulk from NECC without using patient- specific individual prescriptions as required by law. In addition, the Complaints aver that as a result of Box Hill Defendant's conduct, Plaintiffs were administered contaminated products causing serious injuries and, in some cases, death.

The Complaints set forth the following causes of action against the Box Hill Defendants[6]: Count I – Medical Malpractice - Negligence; Count II – Informed Consent; Count III – Battery; Count IV – *Respondeat Superior* as to NECC; Count V – Civil Conspiracy; Count

[3] MGL Ch. 94C §1 et seq.
[4] MGL Ch. 93A.
[5] Maryland Consumer Protection Act – Codified by Md. Code Ann., Com. Law Art. ("CL"), §§ 13-101, et seq.
[6] "Kashi" Complaint used for reference/representative purposes unless noted otherwise.

VI – Strict Liability; Count XI – Violation of Maryland and Massachusetts State Consumer Protection Statutes; Count XIII – Wrongful Death; Count XIII – Loss of Consortium[7]. Each Count is sufficiently pled, establishing a plausible entitlement to relief, especially where the allegations are to be construed in the light most favorable to Plaintiffs. As explained below, the parties stipulated to the dismissal of certain counts.

On January 13, 2015, Box Hill Defendants filed the instant Rule 12 (b)(6) Motion to Dismiss all Counts[8]. Based on the Courts prior decisions, the parties met and conferred and stipulated to the disposition of various Counts.

On April 17, 2015, the Court approved a Stipulation by counsel, granting Defendants' Motions to Dismiss as to claims for Battery, *Respondeat Superior*, and Civil Conspiracy and dismissing those counts in Plaintiffs' Complaints against Box Hill Defendants. The Court denied the Defendants' Motions to Dismiss as to claims for Negligence, Informed Consent, Wrongful Death, and Loss of Consortium.

The Court further ordered that the Plaintiffs had forty-five (45) days to file their opposition to Defendants' Motion to Dismiss claims for Strict Liability, violations of Maryland's Consumer Protection Statutes, violations of Massachusetts' Consumer Protection Statutes and claims for Punitive Damages.[9] By Order dated June 2, 2015, the Court granted an extension of time, until June 5, 2015, for Plaintiffs to file the opposition to the Motion to Dismiss.[10]

[7] "Dreisch" Complaint used for reference/representative purposes for Loss of Consortium claims.

[8] Dkt. No. 1639 - Motion to Dismiss.

[9] Dkt. No. 1780 - Judge Rya W. Zobel Order entered.

[10] Dkt. No. 1912- Judge Rya W. Zobel Order (Electronic Order- no document attached).

As demonstrated below, the Box Hill Plaintiffs have more than adequately stated their claims for Strict Liability, Violations of Maryland and Massachusetts Consumer Protection Statutes and Punitive Damages. Box Hill Defendants' Motion to Dismiss these claims should be denied.

STANDARD OF REVIEW

In deciding a motion to dismiss, "a court does not rule on the evidentiary sufficiency of a complaint, only on whether its factual and legal assertions allege 'a plausible entitlement to relief.'" *Balerna v. Gilberti*, CIV.A. 09-10075-RGS, 2010 WL 4878286, at *4 (D. Mass. Nov. 24, 2010); (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 559 (2007)). In considering a motion to dismiss, the court should "treat as true all well-pleaded facts, viewing those facts in the light most favorable to the plaintiff, and drawing all reasonable inferences therefrom for [plaintiff]." *Knowlton v. Shaw*, 704 F.3d 1, 3 (1st Cir. 2013) (*citing Gagliardi v. Sullivan*, 513 F.3d 301, 305 (1st Cir.2008)). Under *Twombly*, a complaint need only allege "enough factual matter (taken as true) to suggest" the validity of the claim. *Twombly*, 550 U.S. at 557. "To justify a dismissal on any Civ. R. 12(b)(6) motion, the court must find beyond doubt from the complaint that the plaintiffs can prove no set of facts entitling them to relief." *Saylor v. Providence Hosp.*, 113 Ohio App. 3d 1, 3-4, 680 N.E.2d 193, 194-95 (1996).

LAW AND ARGUMENT

I. Box Hill Defendants' Sale and Administration of Contaminated MPA to Plaintiffs is Subject to an Action Based on Strict Liability in Tort, Pursuant to Maryland Product Liability Law

The Box Hill Defendants sold and administered contaminated MPA to Plaintiffs in the above-captioned cases[11] who have alleged facts sufficient to maintain a cause of action against these Defendants under the theory of strict liability (Count VI of the Complaints).

In *Phipps v. General Motors Corp., 278 Md. 337, 363 A.2d 955* (1976), the Court of Appeals of Maryland (Maryland's highest court) adopted strict liability as a cause of action as set forth in *Restatement (Second) of Torts* (1965) §402A, which provides that "[o]ne who sells any product in a defective condition unreasonably dangerous to the user or consumer… is subject to liability for physical harm thereby caused to the ultimate user or consumer … if the seller is engaged in the business of selling such a product…." Under Maryland law, the doctrine of strict liability focuses primarily on the product and whether or not it can be deemed defective and not on the conduct of the manufacturer or seller. *Phipps*, 278 Md. at 344.

The *Phipps* Court stated, "[T]here is no reason why a party injured by a defective and unreasonably dangerous product, which when placed on the market is impliedly represented as safe, should bear the loss of that injury when the seller of that product is in a better position to take precautions and protect against the defect. Yet this may be the result where injured parties are forced to comply with the proof requirements of negligence actions or are confronted with the procedural requirements and limitations of warranty actions. Therefore, we adopt the theory of strict liability as expressed in §402A of the Restatement (Second) of Torts." *Id.*, at 352-353.

[11] Count VI (Strict Liability) is alleged in the cases filed against the Box Hill Defendants in which the Motions to Dismiss were filed, with the exception of *Handy v. Box Hill Surgery Center, LLC, et al*..

To prevail in a strict liability claim under Maryland law, one must allege and prove the elements set forth in § 402A: (1) the product was in defective condition at the time that it left the possession or control of the seller, (2) that it was unreasonably dangerous to the user or consumer, (3) that the defect was a cause of the injuries, and (4) that the product was expected to and did reach the consumer without substantial change in its condition. *Id.* In the cases at bar, the Box Hill Defendants may be held liable under the doctrine of strict liability for the sale to Plaintiffs of the contaminated MPA. Defendants purchased MPA in a defective condition, which was unreasonably dangerous to Plaintiffs, which was administered to the Plaintiffs in the same condition as when purchased by Defendants, and which caused catastrophic injuries to all eight of the Maryland Plaintiffs, as well as the deaths of four of these victims.

Defendants argue that they are not subject to strict liability because they provide medical services and are not sellers of goods, and more particularly the MPA they injected into their patients. The Court has previously confronted similar arguments made by clinics in Ohio and Tennessee and firmly rejected the notion that clinics facing claims of strict liability cannot be sellers of MPA they injected into their patients.[12] The arguments advanced now by these Defendants should be similarly rejected as they have failed to carry their burden of showing how they are any different from clinics in these other states. Defendants ignore these prior rulings of the Court and incorrectly rely on two Maryland cases, *Roberts v. Suburban Hospital Assoc.*, 73 Md. App. 1, 532 A.2d 1081 (1987), and *Burton v. Artery Company*, 279 Md. 94, 367 A.2d 935 (1977). See *Defendants' Memorandum of Law in Support of their MTD*, page 24, Document 1640.

[12] *See* Dkt. No. 1360 at P25-31; Dkt. No. 1643 at P9.

In *Roberts*, *supra*, a hemophiliac received blood transfusions in 1985 at Suburban Hospital in Maryland and subsequently was diagnosed as having acquired AIDS through the sale and transfusion of contaminated blood. Roberts filed suit against the hospital for his injuries based on strict liability, breach of implied warranties of merchantability and fitness, and negligence. 532 A.2d at 1082. The Circuit Court dismissed all counts and Roberts appealed.

In affirming the lower court's decision[13], the Court of Special Appeals adopted the reasoning in what it termed "the seminal case", *Perlmutter v. Beth David Hospital*, 308 N.Y. 100, 123 N.E.2d 792 (1954), in which the plaintiff sued the hospital for breach of implied warranties of fitness and merchantability, arguing that as part of general medical care she received a contaminated blood transfusion and as a result contracted hepatitis. The plaintiff argued that the transfusion was a sale of goods, and the New York Court of Appeals, in a close 4-3 decision, rejected her arguments. 123 N.E.2d at 794. The *Perlmutter* Court majority "viewed the contractual relationship between hospital and patient as involving a broad spectrum of medical care - 'the patient bargains for, and the hospital agrees to make available, the human skill and physical material of medical science to the end that the patient's health be restored.'"

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[13] The Court in *Roberts* observed: "Had the transfusion occurred on or after July 1, 1986, the issue would have been controlled by statute, for effective that day, the General Assembly rewrote Md. Code Ann. Health-Gen. art., § 18-402 to provide:

> "A legally authorized person who obtains, processes, stores, distributes, or uses whole blood or any substance derived from blood or any substance derived from blood for injection or transfusion into an individual for any purpose is performing a service and is not subject to:
>
> (1) Strict liability in tort;
>
> (2) The implied warranty of merchantability; or
>
> (3) The implied warranty of fitness."

Roberts, 532 A.2d at 1085.

(Citation omitted). "Such a contract, said the majority, 'is clearly one for services, and, just as clearly, is not divisible.'" *Roberts,* 532 A.2d at 1086.

At first blush, it appears that Maryland's *Roberts* decision supports Defendants' argument that they are not subject to strict liability. However, *Roberts* is distinguishable and, in fact, on closer review supports imposing strict liability in the instant cases. Again, quoting from *Perlmutter,* the Court of Special Appeals said: "'The conclusion is evident that the furnishing of blood was only an incidental and very secondary adjunct to the services performed by the hospital and, therefore, was not within the provisions of the Sales Act.'" *Roberts*, 532 A.2d at 1087, quoting *Perlmutter,* 123 N.E.2d at 795. In the cases at bar, however, the MPA product being injected into Plaintiffs was not a secondary item adjunct to the services performed by the Box Hill Defendants. Rather, the medication was the point of the procedure and the Plaintiffs' treatment at Box Hill. The particular steroid medication, itself, was to help alleviate pain and its involvement was far from incidental or marginal. Plaintiffs went to Box Hill for treatment of pain and treatment of Plaintiffs by Box Hill Defendants with MPA clearly involved the sale of goods.

The *Roberts* Court also cited *Burton, supra*, another case Defendants rely on, which stated: "[T]he Court of Appeals made clear that U.C.C. [Uniform Commercial Code] [hereinafter "UCC"] implied warranties applied only to the sale of goods and that a contract involving both the sale of goods and the provision of service would be subject to them only if the sale was the predominant factor, i.e., that 'the thrust, the purpose, reasonably stated, is a transaction of sale with labor incidentally involved.' (citation omitted)." *Roberts,* 532 A.2d at 1088.

In *Burton, supra,* a nurseryman contracted to sell and install more than 600 trees and shrubs and place a substantial amount of sod at the project. The trial court concluded that the

contract in question was a "services" contract to which the four year statute of limitations of the UCC did not apply and entered summary judgment for defendants based on the Maryland three year statute of limitations for civil actions. On appeal, the Court of Appeals of Maryland reversed, holding that the sod, trees, and shrubs were "goods" as defined in UCC §2-105(1):

> "'*Goods*' means all things (including specially manufactured goods) which are movable at the time of identification to the contract for sale other than the money in which the price is to be paid, investment securities (Title 8) and things in action. 'Goods' also includes…growing crops and other identified things attached to realty as described in the section on goods to be severed from realty (§2-107)."

367 A.2d at 937 (Emphasis in original).

In determining whether the contract was for "sales" or "service," the *Burton* Court relied, in part, on *Bonebrake v. Cox,* 499 F.2d 951 (8th Cir. 1974), which involved a contract for the delivery and installation of used bowling equipment. Therein, the Court held that the Special Master erred in ruling that a contract that involved substantial amounts of labor as well as goods, with a lump sum price, did not fall within the statutory scheme of the UCC on the grounds that it was a "mixed" (goods and services) contract.

In *Bonebrake,* the Court referenced R. Nordstrom, *Handbook of the Law of Sales* (1970) (hereafter "Nordstrom"), which discussed the scope and reach of UCC Article 2, as follows:

> "As Nordstrom points out, this section is divided into two parts, the first affirmative, defining the scope and reach of Article 2, the second negative, excluding certain transactions. To come within the affirmative section, the articles (the 'things') must be movable, and the movability must occur at the time of identification to the contract. The applicability of the Code to the April contract is clear from and within its four corners. The 'things' sold are all items of tangible property, normally in the flow of commerce, portable at the time of the contract. **They are not the less 'goods' within the definition of the act because service may play a role in their ultimate use.** The Code contains no such exception. 'Services', continues Nordstrom, id. at 47, 'always play an

> important role in the use of goods, whether it is the service of transforming the raw materials into some usable product or the service of distributing the usable product to a point where it can be obtained by the consumer. **The … definition should not be used to deny Code application simply because an added service is required to inject or apply the product.'** In short, the fact that the contract 'involved substantial amounts of labor' does not remove it from inclusion under the Code on the ground, as the special Master found that 'The Code was (not) meant to cover *** non-divisible mixed contracts of this type.'"

Bonebrake, 499 F. 2d at 958-959 (emphasis added and footnotes omitted).

The *Burton* Court's holding and rationale for concluding that a mixed contract involving both the sale of goods and services comes within the UCC articles on sales provides ample support for finding that strict liability attaches to the Box Hill Defendants sale or distribution of the contaminated MPA. These Defendants' provision of MPA become no less than the sale of a defective product to Plaintiffs simply because the Box Hill Defendants as medical care providers injected it into the Plaintiffs' bodies. There is no principled basis under Maryland law to distinguish the sale of the compounded MPA from a pharmacy's sales of a patent over-the-counter medicine.

A closely analogous circumstance to the Box Hill Defendants providing MPA by injection to Plaintiffs is found in *Newmark v. Gimbel's, Inc.*, 54 N.J. 585, 258 A.2d 697 (1969), quoted by the Maryland Court of Appeals in *Burton, supra*:

> ""A situation arose wherein the plaintiff received a hair treatment at a beauty parlor at which several hair cosmetics were used. One of the cosmetics caused serious injury to the plaintiff's scalp. The court called this transaction a hybrid transaction partaking of incidents of a sale and of a service. 'It was really partly the rendering of services and partly the supply of goods for a consideration.' The rationale of the court was that if the beauty parlor operator had bought and applied the permanent waves solution to her own hair and suffered injury thereby, she would have had an action against the manufacturer-seller of the product because the basic transaction would have arisen from the

> conventional sale. Consequently, it does not make sense to deny a similar right to a patron against the beauty parlor operator or the manufacturer when the purchase and sale were made in anticipation and for the purpose of use of the product on the patron who should be ultimately charged for its use. Common sense would seem to dictate that such a patron would be deemed to be a consumer as to both the manufacturer and the beauty parlor operator." "

Burton, 367 A.2d at 942, *quoting*, A. Squillante and J. Fonseca, *Williston on Sales* § 5-6 (4th ed. 1973) at 104-05. Like the consumer at the beauty parlor who was injured by a product used for a hair treatment, Plaintiffs should have the ability to seek damages from the Box Hill Defendants both as sellers of the MPA and as parties who administered the contaminated product.

Box Hill Defendants argue in the motion to dismiss that they are not sellers and that strict liability does not apply because Defendants did not charge Plaintiffs separately for the MPA in the epidural injection procedures.[14] However, combined or lump sum billing is not decisive in reaching a conclusion on whether the sale of a product or a service predominates. For example, in *Bonebrake,* the Court discussed combined pricing for goods and services in a case "involving a contract for the sale of concrete and 'all labor to pour and finish,' both at a stated price." 400 F.2d at 958, quoting from *Port City Construction Co. v. Henderson,* 48 Ala. App. 639, 266 So.2d 896 (1972) (the contract was held to be in essence a contract for sale of a product, although it included an agreement for work and labor). *Bonebrake,* 400 F.2d at 959.

Regarding whether or not the UCC applies to "non-divisible" mixed goods and services contracts, the *Bonebrake* court observed that there are many cases addressing this issue and said:

> "The test for inclusion or exclusion is not whether they are mixed, but, granting that they are mixed, whether their predominant factor, their thrust, their purpose, reasonably stated, is the rendition of service, with goods incidentally involved (e.g., contract with artist for painting) or is a transaction of sale, with labor incidentally involved (e.g., installation of a water heater in a bathroom). The contract before us, construed in accordance with the

[14] Defendants' Memorandum of Law in Support of their MTD, page 24, Dkt. No. 1640.

> applicable standards of the Code, is not excluded therefrom because it is 'mixed,' and, moreover, is clearly for the replacement of equipment destroyed by fire, i.e. 'goods' as defined by the Code."

400 F.2d at 960 (footnotes omitted). The Court of Appeals of Maryland adopted these criteria in *Burton, supra*, concluding that the trees, shrubs, and sod were goods and that the contract to install them was more analogous to the installation of a water heater in a bathroom (a product sale) than to a contract with an artist for a painting (a service). 367 A.2d at 946.

The case at hand is clearly distinguishable from *Roberts v. Suburban Hospital Assoc., supra*, in which the Court determined that a blood transfusion was such an integrated procedure that the blood (product) and the transfusion (service) could not be separated. Whether it is said that the patient received blood, received a blood transfusion, was transfused, or received a transfusion, the meaning is the same, *i.e.*, blood or a blood derivative was administered. Or, "[t]o draw from Gertrude Stein, a blood transfusion is a blood transfusion is a blood transfusion is a blood transfusion." *Id.*, 532 A.2d at 1089. The case before us, however, is a totally different matter. When a patient is said to have received an injection, the question immediately begged is "… injection of what product?" Thus it is the product injected that is the predominant factor, especially in a tainted or adulterated medication case. Here it is the NECC MPA and not the doctor's skill in administering it that is the crux of the case.

The facts before the Court are that the Box Hill Defendants sold MPA to each of the Plaintiffs to treat pain, and charged the plaintiffs fees for supplying and administering it. Plaintiffs had the right to believe that Box Hill Defendants were reputable sellers and would stand behind the goods it was supplying. In adopting strict liability in Maryland, the Court in *Phipps, supra*, quoted from comment c to § 402A of the Restatement (Second) of Torts:

> "[P]ublic policy demands that the burden of accidental injuries caused by products intended for consumption be placed upon those who market them, and be treated as a cost

> of production against which liability insurance can be obtained; and that the consumer of such products is entitled to maximum of protection at the hands of someone, and the proper persons to afford it are those who market the products."

Phipps, 278 Md. at 352-353.

In sum, the Box Hill Defendants can be found under Maryland law to be sellers of the contaminated MPA it obtained (illegally) in bulk from NECC and administered to their patients, including Plaintiffs. The MPA was expected to and did reach the Plaintiff consumers without substantial change in condition (as it was dispensed by NECC in sealed vials). The contaminated MPA was unreasonably dangerous to the Plaintiff consumers and ultimately caused catastrophic injuries and/or death to the consumers. As the seller and dispenser of contaminated MPA, the Box Hill Defendants can be found strictly liable under Maryland products liability law. Therefore, the Box Hill Defendants' motion to dismiss Count VI of the Complaints should be denied.

II. Plaintiffs' Claims for Violation of the Maryland Consumer Protection Act are in Accordance with Maryland Statutes and Case Law and Therefore Should Not Be Dismissed

The Box Hill Defendants, citing *Scull v. Doctors Groover, Christie & Merritt, P.C.,* 205 Md.App. 567, 45 A.3d 925 (2012), claim that they are not subject to the Maryland Consumer Protection Act (hereinafter "MCPA") because the Act expressly states that it does not apply to the professional services of medical or dental practitioners and because Maryland courts have dismissed claims for services indirectly related to the provision of professional services. This, however, is no longer the law of Maryland.

Maryland courts have more recently held that "the exclusion in CL § 13-104(1) applies only to the actual professional services of a physician. The commercial aspects of a medical practice, such as compliance with laws concerning who may be billed and how, are not exempt

from the Consumer Protection Act. When those billing practices involve unfair or deceptive practices, as defined in the Consumer Protection Act, the medical practice may be subject to a private action brought by a person injured by the violation." *Scull v. Groover, Christie & Merritt, P.C.*, 435 Md. 112, 132, 76 A.3d 1186 (2013). Plaintiffs' MCPA claims against Box Hill Defendants here more closely relate to their business practices than to their professional services.

The purpose of MCPA is to set minimum statewide standards for the protection of consumers across the State to maintain their health and welfare. CL §13-102(b)(1)(3). Maryland's Act is to be applied liberally to promote its purpose. CL §13-105. While there is an exemption for professional services of specified professions, including medical practitioners, CL §13-104(1), as indicated in *Scull*, the exemption is narrow in scope. Though "professional services" is not defined in the MCPA, legislative history pertaining to related CL §13-408, explained that the intended scope of "professional services" meant the "quality of care rendered by the heath care provider in the marketplace, but it does not apply to the commercial or entrepreneurial services, such as billing, reimbursement, or advertising and marketing." *Scull* at 1194.

Here, the sale and administration of NECC's contaminated MPA that Box Hill illegally procured and misrepresented to Plaintiffs or their decedents comes readily within the MCPA's prohibitions. CL § 13-105. The MCPA prohibits unfair or deceptive trade practices, including (but not limited to):

1. False … or misleading oral or written statement… or other representation of any kind which has the capacity, tendency, or effect of deceiving or misleading consumers;
2. Representation that consumer goods… have a sponsorship, approval, accessory, characteristic, ingredient, use, benefit, or quantity which they do not have;
3. Consumer goods are of a particular standard, quality, grade… which they are not;
4. Failure to state a material fact if the failure deceives or tends to deceive;

> 5. Deception, fraud, false pretense, false premise, misrepresentation, or knowing concealment, suppression, or omission of any material fact with the intent that a consumer rely on the same in connection with the promotion or sale of any consumer goods ….

CL §13-301(1)-(3), (9).

Upon information and belief, in order to increase their profits, Box Hill Defendants made the business decision to mail-order purchase preservative-free MPA from NECC in bulk and to do so, willingly and knowingly used bogus prescriptions to circumvent Massachusetts' pharmacy laws that required patient- specific prescriptions and prohibited compounding pharmacies dispensing "office supplies" of prescription medications.

Moreover, Box Hill Defendants recommended Plaintiffs receive MPA injections to relieve their pain, but omitted telling them the material facts that the drugs they would be receiving were compounded, preservative-free drugs, not approved by the FDA, and that the drugs were obtained via mail-order from an out-of-state pharmacy that was neither inspected by the FDA nor accredited by any valid accrediting body. *See, e.g., Kashi Complaint* ¶¶ 191, 192. Thus, Plaintiffs consented to receiving medication based on their belief that the medication was purchased from a reputable source; an FDA approved manufacturer; and would be of high purity and quality. These failures to advise Plaintiffs of material facts deceived them into consenting to receiving administration of the MPA and constituted unfair and/or deceptive business practice under Maryland's Consumer Protection Act. Had Plaintiffs been given the material facts that were omitted, they would not have consented to the injection of the MPA and/or gone to the Box Hill Defendants' business for treatment, would not have developed infections, and would not have been injured and/or died from the contaminated product.

Furthermore, the Box Hill Defendants billed Plaintiffs for the MPA and the injection in a lump sum price but fraudulently recorded in the Plaintiffs' medical records that they had administered FDA-approved Depo-Medrol when in fact they had injected NECC's compounded MPA. *Id.* ¶ 243. In other words, defendants falsely stated in Plaintiffs' medical records that a manufactured pharmaceutical product (of which Depo-Medrol is the brand name) had been administered.

In short, Plaintiffs have alleged violations to the effect that the Box Hill Defendants "deceptively concealed" vital information about the product and made various misrepresentations about the standard, quality, grade, uses and benefits of the contaminated MPA, such as representing to their patients, including Plaintiffs, that they were receiving FDA-approved Depo-Medrol when in fact they injected patients with NECC's compounded MPA, which also happened to be contaminated with fungus. Plaintiffs accordingly have sufficiently alleged violations of the MCPA plausible to entitle them to relief. For these reasons, Plaintiffs request this Court deny the Box Hill Defendants' motion to dismiss their claims under the Maryland Consumer Protection Act.

III. Plaintiffs Have Standing to Bring a Claim Under the Massachusetts Consumer Protection Law Against the Box Hill Defendants

Mass. Gen. Ann. Ch. 93A § 9 provides for civil remedies of consumers and states, in part:

> (1) Any **person**, other than a person entitled to bring action under section eleven of this chapter, who has been injured by another person's use or employment of any method, act or practice declared to be unlawful by section two or any rule or regulation issued thereunder or any person whose rights are affected by another person violating the provisions of clause (9) of section three of chapter one hundred and seventy-six D may bring an action in the superior court, or in the housing court as provided in section three of chapter one hundred and eighty-five C whether by way of original complaint,

> counterclaim, cross-claim or third party action, for damages and such equitable relief, including an injunction, as the court deems to be necessary and proper.

Mass. Gen. Ann. Ch. 93A § 9(1) (emphasis supplied). Section 11[15] of Chapter 93A does not apply to this action because it is only applicable to those engaging in the conduct of trade or commerce that suffer a loss from another also engaging in the conduct of trade or commerce and Plaintiffs were not engaging in the conduct of trade or commerce. As such, this matter is a § 9 action that applies to Plaintiffs (consumers), and the requirement, within § 11, that the sale or transaction occur primarily or substantially in Massachusetts does not apply in § 9 actions. *Snyder v. ADS Aviation Maintenance*, 2000 Mass. Super. LEXIS 5 at *20 (Jan. 10, 2000).

Applicable to § 9, the term "person" includes "natural persons, corporations, trusts, partnerships, incorporated or unincorporated associations, and any other legal entity." Mass. Gen. Ann. Ch. 93A § 1(a). The Supreme Judicial Court of Massachusetts determined that the "1979 amendment substantially broadened the class of persons who could maintain actions" under § 9 and that plaintiffs were entitled to relief pursuant to § 9 if they were injured by any method, act or practice of defendant that was unlawful under § 2. *Van Dyke v. St. Paul Fire and Marine Ins. Co.*, 448 N.E.2d 357, 360 (Mass. 1983).

Plaintiffs satisfy the definition of "person" in § 1(a) and are entitled to relief under § 9 because they were injured by the conduct and omissions of the Defendants, Box Hill Surgery

[15] "Any person who engages in the conduct of any trade or commerce and who suffers any loss of money or property, real or personal, as a result of the use or employment by another person who engages in any trade or commerce of an unfair method of competition or an unfair or deceptive act or practice declared unlawful by section two or by any rule or regulation issued under paragraph (c) of section two may, as hereinafter provided, bring an action in the superior court, or in the housing court as provided in section three of chapter one hundred and eighty-five C, whether by way of original complaint, counterclaim, cross-claim or third-party action for damages and such equitable relief, including an injunction, as the court deems to be necessary and proper." Mass. Gen. Ann. Ch. 93A § 11.

Center, LLC, Ritu T. Bhambhani, M.D., and Ritu T. Bhambhani, M.D., LLC's ("Box Hill Defendants") in submitting false and bogus prescriptions to NECC on NECC's Prescription Order form, thereby unfairly violating governing Massachusetts' regulations, laws and guidelines set forth to protect consumer safety and the integrity dispensing of regulated pharmaceutical products. Once in possession of the illegally obtained office supply of NECC MPA product, the Box Hill Defendants, and again in violation of Massachusetts' pharmaceutical dispensing law, dispensed the medication to the plaintiffs (or their decedents), all the while misrepresenting the nature, quality, and characteristics about NECC's compounded MPA. Thus the Box Hill Defendants exposed unknowing consumers to significant, unnecessary risk of harm and actual harm and injury Massachusetts' pharmacy laws and regulations were adopted to avoid. See e.g., Handy Complaint ¶¶ 4, 132, 140-41, 271, 281. [16]

[16] For example, Plaintiff Handy pleads regarding her late mother, Brenda Rozek, at ¶4:

> The [Box Hill Defendants] named herein are a significant part of the cause of [the 2012 fungal meningitis and infection] epidemic. They, among other things, negligently selected NECC as compounding pharmacy for a difficult medication to compound in a preservative free form, and repeatedly ordered preservative free MPA in so called office supply quantities from NECC in contravention of applicable Massachusetts pharmacy dispensing laws. Among the compounded medication the Health Care Providers obtained from NECC were eighty-five (85) 5ml vials of MPA shipped on or about August 13, 2012 that were dispensed from one or more lots of the three (3) contaminated lots MPA laden with fungus. MPA drawn from one of these vials was then, and without proper and necessary disclosure of the nature and source of the compounded medication and, further, without obtaining proper and intelligent informed consent, injected into Decedent Rozek's body on or about August 31, 2012 as part of a recommended course of pain management treatment by Health Care Provider Dr. Ritu T. Bhambhani, M.D. at the Box Hill Surgery Center. As a result of the administration of the contaminated MPA, Decedent developed a serious fungal infection that progressed into fungal meningitis, which led to her hospitalization and eventual death on September 16, 2012 at age 51.

And further alleges at ¶281:

> As described herein, the Health Care Providers' submitted to NECC bogus or past patient named in order to obtain office supplies of preservative free MPA drugs from NECC in violation of Massachusetts' controlled substances and pharmacy laws and regulations. Such submissions constitute actionable violations of Maryland's and Massachusetts' respective consumer protection statutes.

Section 2(a) of Chapter 93A provides "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful." Mass. Gen. Ann. Ch. 93A § 2(a). Trade and commerce "shall include the advertising, the offering for sale, rent or lease, **the sale**, rent lease **or distribution** of any services and **any property**, tangible or intangible, real, personal or mixed, any security as defined in subparagraph (k) of section four hundred and one of chapter one hundred and ten A and any contract of sale of a commodity for future delivery, and any other article, commodity, or thing of value wherever situate, and shall include any trade or commerce directly or indirectly affecting the people of this commonwealth." Mass. Gen. Ann. Ch. 93A § 1(b) (emphasis supplied).

While § 1(b) includes trade or commerce "directly or indirectly affecting the people" of Massachusetts, trade or commerce is notably not limited only to the people of Massachusetts and includes "sales" to all people, including non-residents of Massachusetts. As stated above, Plaintiffs alleged that the Box Hill Defendants' conduct constitutes a violation of Mass. Gen. Ann. Ch. 93A § 2(a). Therefore, the Box Hill Defendants' Motion to Dismiss Plaintiffs' Consumer Protection Violation under Massachusetts Law should be denied because Plaintiffs are entitled to bring a claim under Mass. Gen. Ann. Ch. 93A § 9.

IV. Plaintiffs Have Alleged Sufficient Facts to Support a Claim for Punitive Damages Under Maryland Law

Under Maryland law "[p]unitive damages … seek to punish a party 'whose conduct is characterized by evil motive, intent to injure, or fraud, and to warn others contemplating similar conduct of the serious risk of monetary liability.'" *Garcia v. Foulger Pratt Development, Inc.*, 854 A.2d 16, 46 (Md. 2003) (quoting *Owens-Illinois, Inc. v. Zenobia*, 601 A.2d 633 (Md. 1992)). In order to recover punitive damages the plaintiff must establish actual malice – "'conduct

characterized by evil motive, intent to injure, ill will, or fraud.'" *Id*. (quoting *Owens-Illinois, Inc.*, 601 A.2d at 652 n. 20).

In this case, and again using Plaintiff Handy's wrongful death and survival action complaint for illustration purposes, Plaintiffs allege:

> 195. At all times material hereto, Defendants purchased, stored, handled, sold, used, administered, and/overall possessed and utilized contaminated MPA with willful and intentional disregard to the individual rights of Decedent, warranting an award of punitive damages to Decedent.
>
> ***
>
> 197. Defendants thereby acted with **oppression, fraud and malice** toward Decedent, therefore, Plaintiff requests additional damages for the sake of example and for the purpose of punishing Defendants for their conduct, in amounts sufficiently large to be an example to others and to deter these Defendants and others from engaging in similar conduct in the future.
>
> 198. The above described acts and omissions on the part of the Defendants were reckless and intentional. Defendants were aware of, but constitutes disregarded, a substantial and unjustifiable risk of such a nature that their disregard constitutes a gross deviation from the standard of care that an ordinary person would exercise under all the circumstances. Plaintiffs therefore are entitled to an award of punitive damages against the Defendants.

Handy Complaint at ¶¶ 195-198 (emphasis supplied). It is therefore unfounded for the Box Hill Defendants to file this instant Motion seeking to dismiss Plaintiffs' punitive damage claim, when Plaintiffs' Complaint specifically alleges that Defendants acted with "fraud and malice." The Box Hill Defendants' Motion to Dismiss instead argues facts and seeks to have the Court make findings of fact, which are reserved for the jury. Such arguments are inappropriate at the motion to dismiss stage. Accordingly, the Box Hill Defendants' Motion to Dismiss Plaintiffs' punitive damage claims should be denied because Plaintiffs' Complaint alleges sufficient facts to establish a claim for punitive damages.

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that this Court deny the Box Hill Defendants' Motion to Dismiss Strict Liability, Violations of Maryland and Massachusetts Consumer Protection Statutes and Punitive Damages. In the alternative, should this Court determine that Plaintiffs' allegations are deficient, Plaintiffs respectfully request the opportunity to amend their complaints to provide further allegations.

Date: June 5, 2015

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I, Sharon L. Houston, hereby certify that I caused a copy of the above to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: **June 5, 2015**

/s/ Sharon L. Houston
Sharon L. Houston, Esq.